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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,738	09/29/2003	Tony Romeo	14233.12USU1	7816
23552	7590	06/02/2006	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			VOGEL, NANCY S	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/675,738

Applicant(s)

ROMEO ET AL.

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.  
4a) Of the above claim(s) 5-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/13/04</u> . | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

Claims 1-44 are pending in the case.

Receipt of the Information Disclosure Statement on 1/13/04 is acknowledged.

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-4, in the reply filed on 3/13/06 is acknowledged. The traversal is on the ground(s) that claims in other Groups are classified in the same class and subclass as the elected Group. This is not found persuasive because the search required for examination of claims in the biotechnology area must include the non-patent literature and therefore is not limited to the search of patent class and subclasses. Therefore, the fact that certain Groups are classified in the same class and subclass in the patent system of classification does not fairly reflect the range of search required.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/13/06.

### ***Sequence compliance***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1)

and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences are set forth in the specification and drawings that lack sequence identifiers. (See pages 12, 14, 15, 16 and Figure 10). It is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP 244.02). If the sequences are already present in the sequence listing, it would be remedial to amend the Brief Description of the Drawings to include the appropriate sequence identifiers. Applicants are required to comply with all of the requirements of 37 CFR 1.821 - 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F. R. 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Romeo (WO 95/04074).

Romeo disclose a method of “altering the metabolism or structural or functional properties of a cell” comprising altering genetic expression of *csrA*, including increasing

or decreasing the CsrA levels in a biofilm-forming bacterial strain (see claims, see page 9 lines 15-27). It is considered that the biofilm formation is reduced in this strain when the *csrA* gene product level is increased, or increased when the *csrA* gene product level is decreased, since the instant specification discloses that biofilm reduction or increase results from changes in *csrA* expression.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Romeo (US Patent 5,684,144).

Romeo disclose a method of increasing biofilm formation by decreasing CsrA levels in a biofilm-forming bacterial strain, and a method of decreasing biofilm formation by increasing CsrA levels in a biofilm-forming bacterial strain (see col. 5, lines 14-34; see Examples 3, 9, 10, 11). The plasmid pCSR10 causes overexpression of the CsrA protein; the mutation disclosed as TR1-5 is a *csrA* mutation.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Altier et al. (Infection and Immunity, Dec. 2000, Vol. 68, No. 12, p. 6790-6797).

Altier et al. disclose a method of increasing biofilm formation by decreasing CsrA levels in a biofilm-forming bacterial strain (a *csrA* mutant) (see page 6792, last paragraph of first col., through second col.). Altier et al. disclose a method of decreasing biofilm formation by increasing CsrA levels in a biofilm-forming bacterial strain (a strain in which *csrA* is overexpressed) (see page 6793, last paragraph first col., through second col.).

Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Tatarko et al. (Curr. Microbiol. Vol. 43 (2001)., pp. 26-32).

Tatarko et al. disclose a method of increasing biofilm formation by decreasing CsrA levels (the strain NST CSR(*csrA::kanR*) in a biofilm-forming bacterial strain (see abstract, see Fig. 2).

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Jackson ("The effect of CsrA on Biofilm Development in *Escherichia coli*" , Doctoral Dissertation, Graduate School of Biomedical Sciences, University of North Texas Health Science Center at Fort Worth, May 2001).

Jackson disclose a method of increasing biofilm formation by decreasing CsrA levels in a biofilm-forming bacterial strain, and a method of decreasing biofilm formation by increasing CsrA levels in a biofilm-forming bacterial strain (a strain in which *csrA* is overexpressed (page 61-63).

Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Jackson et al. (*J. Bacteriol.*, Jan 2002, Vol. 184, No. 1, pp. 290-301).

Jackson et al. disclose a method of increasing biofilm formation by decreasing CsrA levels in a biofilm-forming bacterial strain (a *csrA* mutant) (see page 294, columns 1-2). Jackson et al. disclose a method of decreasing biofilm formation by increasing CsrA levels in a biofilm-forming bacterial strain (a strain in which *csrA* is overexpressed) (see page 294, col. 2- page 295 col. 1).

### ***Conclusion***


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

N. Vogel  
5/22/06

  
NANCY T. VOGEL  
PRIMARY EXAMINER

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